

Acute Contaminant Breakthrough in Double-Pass Reverse Osmosis Water for Online Hemodiafiltration: A Monitoring Blind Spot, “The Samovar Makers’ Phenomenon”

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To the Editor,

Double-pass reverse osmosis (RO) is regarded as a definitive barrier against waterborne contaminants in hemodialysis, and inline conductivity monitoring is widely relied upon as the primary real-time safeguard of this barrier.^{1,2} We report an episode in which this assumption failed at an outpatient dialysis center providing maintenance hemodialysis and online hemodiafiltration (HDF) to 45 patients with end-stage renal disease, illustrating that conductivity monitoring alone may not reliably detect complex, evolving contaminant mixtures originating from upstream environmental sources.² The automated inline conductivity sensor did not trigger an alert because its alarm threshold was calibrated to a total conductivity range that did not account for the compensatory ionic composition of this contaminant mixture, and because the sensor was positioned downstream of the double-pass RO stages, where blending of permeate masked the localized breakthrough.

A cluster of pyrogenic reactions during online HDF prompted an immediate engineering audit of the water treatment train (multi-media sand filtration, dual-bed activated carbon, water softener, 5-µm pre-filter, and medical-grade double-pass RO). The audit excluded localized mechanical failure: membrane modules were structurally

intact, pressure balances were within specification, O-rings showed no leakage, and pretreatment testing showed no chlorine/chloramine breakthrough. Split post-RO permeate samples were collected under documented chain of custody and analyzed by an ISO/IEC 17025-accredited reference laboratory (ICP-MS for trace elements, ion chromatography for anions, flame photometry for sodium, and heterotrophic plate counts). We also retrospectively reviewed the charts of all 45 exposed patients.

Permeate concentrations exceeded AAMI/ISO 13959:2020 thresholds for sodium, nitrate, fluoride, calcium, magnesium, and heterotrophic plate count;¹ arsenic and chromium remained at or below their regulatory ceilings (Table 1). Clinically, 11.1% of patients (5/45) developed intradialytic pyrogenic reactions — high-grade fever, rigors, vomiting, and hypotension — during online HDF. The wider cohort showed a temporally associated pattern of erythropoietin-resistant anemia, new peripheral neuropathic symptoms, and intradialytic cardiovascular instability—findings consistent with trace-element/heavy-metal toxicity,³ hard-water syndrome,⁴ nitrate-related intradialytic hypotension,⁵ dialysis encephalopathy/neurotoxicity,⁶ and nitrate-induced methemoglobinemia/refractory anemia;⁷ all resolved after remediation.

Table 1. Post-RO permeate concentrations relative to AAMI/ISO 13959:2020 thresholds¹

Parameter	AAMI/ISO 13959 Ceiling	Mean Result	Status	Unit
Sodium	70.0	354.0	Exceeded	mg/L
Nitrate	2.0	30.65	Exceeded	mg/L
Fluoride	0.20	0.955	Exceeded	mg/L
Calcium	2.0	8.40	Exceeded	mg/L
Magnesium	4.0	5.05	Exceeded	mg/L
Heterotrophic plate count	< 100	750	Exceeded	CFU/mL
Arsenic	0.005	0.005	At ceiling	mg/L
Total chromium	0.014	0.012	Below ceiling	mg/L

Immediate actions included suspension of online HDF, a clean-in-place (CIP) cycle with replacement of the double-pass RO membrane cartridges and pre-filters, softener resin regeneration, and reinforced pretreatment monitoring, followed by serial independent water testing before HDF was resumed. Repeat testing over the following weeks showed progressive normalization of permeate quality. We note, however, that this improvement coincided both with the corrective CIP/filter-replacement cycle and with a seasonal shift in the relative contribution of the two feed-water sources (deep well versus surface water); the corrective intervention and a possible seasonal reduction in source contamination therefore cannot be fully disentangled as explanations for the observed recovery.

We propose the term “Samovar-makers’ Alley Phenomenon” to describe the uncontrolled industrialization and urbanization occurring in peripheral districts of large cities. This pattern, exemplified by the Samovar-makers’ Alley (Kucheh Samovar-sazan) in Mashhad, Iran, leads to contamination of local water, soil, and air supplies, posing substantial health risks to surrounding residents and vulnerable patient populations, particularly those receiving dialysis therapy.

Based on this experience, we suggest that: (1) dialysis centers in environmentally vulnerable or industrially adjacent areas should not rely on inline conductivity monitoring alone, and should supplement it with periodic independent chemical and microbiological testing of post-RO permeate;^{1,2} (2) where online HDF is performed, routine endotoxin/LAL surveillance should be considered, given the reduced protective margin compared with conventional hemodialysis;¹ and (3) regulatory bodies may wish to reconsider whether current AAMI/ISO trace-element thresholds, derived largely for populations with intact renal clearance, adequately protect anuric ESKD patients exposed repeatedly, over years, to water at or near these ceilings.^{1,3,6}

This report is limited by the absence of direct endotoxin quantification and patient-level toxicology, and by its single-center, retrospective, uncontrolled design; causal inference should

therefore be made cautiously. Nonetheless, we believe this case is a useful patient-safety signal for centers operating in similar environmental settings, and that the Samovar-makers’ Alley Phenomenon may be relevant to other peripheral urban districts undergoing similar unplanned industrialization.

CONFLICT OF INTEREST

The author declares no competing interests.

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